

### **REMARKS**

Claims 1-21 constitute the pending claims in the present application. The Examiner has withdrawn claims 4-9 and 11-13. Claims 1-3, 10, and 14-21 have been rejected under 35 U.S.C. 103. Claims 15 and 19 have been canceled. Claims 1, 2, 14 and 18 have been amended to more clearly and distinctly point out the claimed subject matter. Support for these amendments can be found, for example, in the specification on p. 6, lines 17-23, p. 7, lines 22-25, p. 9, lines 27-32, p. 10, lines 1-22, p. 17, lines 14-17, and p. 25, lines 6-12. Claims 10-13 have been amended to correct an inadvertent typographical error and correct claim dependency. Applicants assert that these amendments are fully supported by the specification and add no new matter.

Applicants respectfully request reconsideration in view of the foregoing amendments and following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the Office Action.

Rejection based on 35 U.S.C. 103(a). Applicants acknowledge with appreciation the withdrawal of the rejection to claims 1-3, 10, and 14-17 for obviousness in light of Smith et al. (U.S. Patent No. 5,378,475) ("Smith").

Rejection based on 35 U.S.C. 103(a). Applicants acknowledge with appreciation the withdrawal of the rejection to claims 18-21 for obviousness in light of Chen et al. (U.S. Patent No. 5,902,598) ("Chen").

Rejection based on 35 U.S.C. 103(a). The Office has maintained its rejection of claims 1-3, 10, 14 and 16-17 under 35 U.S.C. 103(a) as being obvious over Smith et al. (U.S. Patent No. 5,378,475) ("Smith") in view of Wong et al. (U.S. Patent No. 6,331,313) ("Wong"). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

Smith discloses the method and device for treating a mammalian organism in order to obtain a desired local or systemic physiological or pharmacological effect wherein the device includes an inner core or reservoir comprising the effective agent; a first coating layer, which is essentially impermeable to the passage of the effective agent; and a second coating layer, which is permeable to the passage of the effective agent. The first coating layer covers the inner core; however, at least a small portion of the inner core is not coated with the first coating layer. The

second coating layer essentially completely covers the first coating layer and the uncoated portion of the inner core. (abstract, U.S. 5,378,475).

Wong discloses controlled release devices which have a core comprising a drug. In addition, a polymeric outer layer which is substantially impermeable to the entrance of an environmental fluid and substantially impermeable to the release of the drug during a delivery period covers the core. Drug release is effected through an orifice in the outer layer (abstract, U.S. 6,331,313). Wong does not teach a device that includes a matrix material that is admixed with the drug to inhibit or prevent decomposition, as recited in the pending claims.

Conversely, pending independent claims 1 and 2 and dependent claims 3 and 10 recite a sustained release drug delivery device adapted for implantation in or adjacent to the eye of a patient, the drug delivery device comprising: (i) an inner drug core comprising an adrenergic agent; (ii) a first coating layer; and (iii) one or more additional coating layers that are permeable to the passage of the adrenergic agent and *comprise an adrenergic agent that is the same or different as the adrenergic agent of the inner drug core*. Neither Smith or Wong, either alone or in combination, teach or suggest a second layer *comprising anything*, let alone an adrenergic agent that is the same or different as the adrenergic agent of the inner drug core. In fact, Wong is silent with regard to any other layer beyond its first polymer layer.

Independent claim 14 and dependent claims 15-17 recite a sustained release drug delivery device adapted for insertion in or adjacent to the eye of the patient, the drug delivery device comprising: (i) an inner drug core comprising an adrenergic agent; (ii) a layer that is partially or substantially permeable to the passage of the adrenergic agent and *comprise an adrenergic agent that is the same or different as the adrenergic agent of the inner drug core*. Neither Smith or Wong teach or suggest a layer comprising anything, let alone an adrenergic agent.

While both Smith and Wong recite an inner core containing an active agent covered by a polymeric layer, neither teaches a layer that comprises an adrenergic agent that is the same or different as the adrenergic agent of the inner drug core. Thus, because Smith in view of Wong does not teach or suggest all of the limitations recited in the pending claims, Applicants submit that the skilled artisan would have no expectation of success in modifying Smith as presently claimed. Accordingly, Applicants request that the Examiner withdraw the above obviousness rejection.

Rejection based on 35 U.S.C. 103(a). The Office has maintained its rejection of claims 18 and 20-21 under 35 U.S.C. 103(a) as being obvious over Chen et al. (U.S. Patent No. 5,902,598) ("Chen") in view of Wong et al. (U.S. Patent No. 6,331,313) ("Wong"). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

Chen discloses a method and device for sustained drug release that includes an inner core reservoir of effective agent, a first coating layer permeable to the passage of the effective agent, a second impermeable coating layer, and a third coating layer permeable to the passage of the effective agent (abstract, U.S. 5,902,598). Chen does not teach or suggest a device that contains a layer which *includes an adrenergic agent that is the same or different as the adrenergic agent of the inner core* as recited in pending claims 18 and 20-21. In fact, Chen is silent with regard to any substance within either its impermeable coating layer or its permeable coating layer.

Furthermore, as discussed above, Wong also does not teach a device which includes an outer layer that comprises an adrenergic agent that is the same or different as the adrenergic agent of the inner core. In fact, like Chen, Wong is silent with regard to its layer containing anything, let alone an adrenergic agent. Thus, because Chen in view of Wong does not teach or suggest all of the limitations of the pending claims, Applicants submit that the skilled artisan would have no expectation of success in modifying Chen as presently claimed. Accordingly, Applicants request reconsideration of the above obviousness rejection.

Co-pending applications. Lastly, Applicants, in accordance with the on-going duty of disclosure, would like to direct the Examiner's attention to a Final Office Action issued on December 19, 2008 in co-pending U.S. application 10/762,421.

### CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617.951.7000. A one-month petition for extension of time and authorization of the prescribed fee are being filed herewith. Please charge any further fees due or credit any overpayments to

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our Deposit Account No. 18-1945, under Order No. CDSI-P01-041 from which the undersigned  
is authorized to draw.

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Respectfully submitted,

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